

Appl. No. 09/964,554  
Amdt. dated October 8, 2003  
Reply to Office action of April 9, 2003

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This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

103 ✓ 1. (Currently Amended) A method of treating a kidney disease comprising administering a composition comprising an effective amount of isolated and purified soyasaponin B<sub>b</sub> as the sole active ingredient to an animal in need thereof.

103 ✓ 2. (Original) A method according to claim 1 wherein the kidney disease is polycystic kidney disease.

~~3. (Cancelled)-A method according to claim 2 further comprising administering an effective amount of soyasaponin B<sub>a</sub> and/or soyasaponin-B<sub>c</sub>.~~

103 ✓ 4. (Original) A method according to claim 1 wherein the soyasaponin B<sub>b</sub> is given in an amount from about 1 to about 10 g/day.

~~5. (Cancelled) A pharmaceutical composition for use in treating a kidney disease comprising an effective amount of isolated and purified soyasaponin B<sub>b</sub> in admixture with a suitable diluent or carrier, wherein the kidney disease is selected from the group consisting of polycystic kidney disease, acquired renal cystic disease, medullary cystic disease of the kidney, autosomal recessive polycystic kidney disease, hereditary interstitial nephritis, other inherited disorders in which PKD forms part of the symptomatology, persons with a potassium-wasting disorder, glomerulonephritis and the group of renal disorders associated with inflammatory and immune dysfunction in the kidney.~~

~~6. (Cancelled)-A pharmaceutical composition according to claim 5 further including s yasaponin B<sub>a</sub> and/or soyasaponin B<sub>c</sub>.~~

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~~7. (Cancelled) A nutraceutical composition for use in treating a kidney disease comprising an effective amount of isolated and purified soyasaponin B<sub>b</sub> in admixture with a suitable diluent or carrier, wherein the kidney disease is selected from the group consisting of polycystic kidney disease, acquired renal cystic disease, medullary cystic disease of the kidney, autosomal recessive polycystic kidney disease, hereditary interstitial nephritis, other inherited disorders in which PKD forms part of the symptomatology, persons with a potassium-wasting disorder, glomerulonephritis and the group of renal disorders associated with inflammatory and immune dysfunction in the kidney..~~

~~8. (Cancelled) A nutraceutical composition according to claim 7 further including soyasaponin B<sub>a</sub> and/or soyasaponin B<sub>c</sub>.~~

a 9. (Previously Amended) A method of isolating soyasaponin B<sub>b</sub> from a sample comprising:

- (a) solubilizing the sample in acidified aqueous alcohol;
- (b) removing polar lipids by liquid chromatography;
- (c) solubilizing the sample from (b) in aqueous alcohol;
- (d) passing the sample from (c) through an anion exchange column;
- (e) eluting the sample absorbed to column in (d) with an acidified aqueous alcohol;  
and
- (f) purifying the sample from (e) by liquid chromatography by passing the sample through a preparative hydrophobic interaction chromatographic column comprising an electrostatically-linked, aliphatic- or alicyclic-substituted anionic or cationic polysaccharide gel and collecting fractions containing soyasaponin B<sub>b</sub>.

10. (Original) A method according to claim 9 wherein the starting sample is soy molasses.

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- a 11. (Original) A method according to claim 9 wherein the sample is solubilized in step (c) in 50-80% ethanol.
- a 12. (Original) A method according to claim 9 wherein the acidified aqueous alcohol is 80% ethanol with 5% formic acid.
- ~~13. (Cancelled) A method according to claim 9 wherein the sample is purified in step (f) by passing the sample through a preparative hydrophobic interaction chromatographic column.~~
- a 14. (Previously Amended) A method according to claim 9 wherein the preparative hydrophobic interaction column is hexadecyltrimethylammonium-substituted SP Sepharose.
- a 15. (Original) A method according to claim 9 wherein the soyasaponin B<sub>b</sub> isolated from step (f) is further purified by preparative liquid chromatography.
- dup. ch. 9.* 16. (Previously Amended) A method according to claim 1 wherein the soyasaponin B<sub>b</sub> is obtained by a method comprising: *not imp.*
- (a) solubilizing the sample in acidified aqueous alcohol;
  - (b) removing polar lipids by liquid chromatography;
  - (c) solubilizing the sample from (b) in aqueous alcohol;
  - (d) passing the sample from (c) through an anion exchange column;
  - (e) eluting the sample absorbed to column in (d) with an acidified aqueous alcohol; and
  - (f) purifying the sample from (e) by liquid chromatography by passing the sample through a preparative hydrophobic interaction chromatographic column

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comprising an electrostatically-linked, aliphatic- or alicyclic-substituted anionic or cationic polysaccharide gel and collecting fractions containing soyasaponin B<sub>6</sub>.

17. (Cancelled) A pharmaceutical composition according to claim 5 wherein the soyasaponin B<sub>6</sub> is obtained by a method comprising:

- (a) solubilizing the sample in acidified aqueous alcohol;
- (b) removing polar lipids by liquid chromatography;
- (c) solubilizing the sample from (b) in aqueous alcohol;
- (d) passing the sample from (c) through an anion exchange column;
- (e) eluting the sample absorbed to column in (d) with an acidified aqueous alcohol; and
- (f) purifying the sample from (e) by liquid chromatography by passing the sample through a preparative hydrophobic interaction chromatographic column comprising an electrostatically-linked, aliphatic- or alicyclic-substituted anionic or cationic polysaccharide gel and collecting fractions containing soyasaponin B<sub>6</sub>.

18. (Cancelled) A nutraceutical composition according to claim 7 wherein the soyasaponin B<sub>6</sub> is obtained by a method comprising:

- (a) solubilizing the sample in acidified aqueous alcohol;
- (b) removing polar lipids by liquid chromatography;
- (c) solubilizing the sample from (b) in aqueous alcohol;
- (d) passing the sample from (c) through an anion exchange column;
- (e) eluting the sample absorbed to column in (d) with an acidified aqueous alcohol; and
- (f) purifying the sample from (e) by liquid chromatography by passing the sample through a preparative hydrophobic interaction chromatographic column comprising an electrostatically-linked, aliphatic- or alicyclic-substituted anionic or cationic polysaccharide gel and collecting fractions containing soyasaponin B<sub>6</sub>.

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~~19. (Cancelled) The composition according to claim 5, wherein the kidney disease is polycystic kidney disease.~~

~~20. (Cancelled) The composition according to claim 7, wherein the kidney disease is polycystic kidney disease.~~

21. (New) A method of treating a kidney disease consisting of administering an effective amount of isolated and purified soyasaponin B<sub>b</sub> to an animal in need thereof.